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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,456	09/19/2003	Douglas P. Cerretti	2517-D	5621
22932	7590	11/20/2006		
IMMUNEX CORPORATION LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119				
			EXAMINER MOORE, WILLIAM W	
			ART UNIT 1656	PAPER NUMBER

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,456	Applicant(s) CERRETTI, DOUGLAS P.	
	Examiner William W. Moore	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 September 2006 has been entered.

Response to Amendment

Applicant's Amendments to the specification filed 8 September overcome the objection of record to the specification. New claims 32-42 are free of the rejections of record under 35 U.S.C. § 112, first paragraph, for lack of enablement as to making and for lack of an adequate written description and free as well of the rejection of record under 35 U.S.C. § 112, second paragraph. The fragment of SEQ ID NO:12 recited in the new claim 42 finds a basis at, e.g., page 17, lines 29 and 30, of the specification. Claims 32-42 remain subject, however, to rejections of record of claims herein under 35 U.S.C. § 101 for lack of a specific, substantial, utility and 35 U.S.C. § 112, first paragraph, for lack of enablement as to use, which are restated below.

Claim Rejections - 35 USC § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 32-42 are rejected for reasons of record under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Applicant's arguments at pages 7-9 of the Response filed 8 September 2006 have been fully considered, together with the publication of Almeida et al., 1996, **Cell**, Vol.

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81, pp. 1095-1104, supplied by Applicant, but they are not persuasive. Applicant suggests that a polypeptide comprising the disintegrin domain of SEQ ID NO:12 might, by analogy with the statement made by Almeida et al. at page 1101, have a specific and substantial utility in mediating sperm-egg surface interactions, or generic cell-cell interactions, because the SVPH-1a polypeptide of SEQ ID NO:12 herein has the general structure of a metalloprotease-disintegrin and the fertilin- α /ADAM1 and fertilin- β /ADAM1 discussed by Almeida et al. are also metalloprotease-disintegrins. Yet there is no indication in the specification of any particular cellular or physiological function of the metalloprotease of SEQ ID NO:12 or of the cellular or physiological function of its included disintegrin domain. The utilities argued at pages 7-9 of the reply are not **specific** to the disintegrin domain within SEQ ID NO:12 as there is no indication that this disintegrin domain can mediate or affect egg-sperm surface interactions and an allegation of a generic utility for this disintegrin domain in mediating or affecting non-specific cell-cell interactions cannot be considered to be a specific utility. Applicant had previously argued that this disintegrin domain might allow specific identification of testis tissue or cells or that its presence somewhere in the testis might have an association with a normal or an abnormal physiological state, or an association with health or disease. Both the previously argued and the currently argued utilities are no more than prospective, potential, utilities where the specification can identify no particular, i.e., specific, utility for the disintegrin domain within SEQ ID NO:12 among the many different functions established for some, but not all, disintegrin domains and there is no showing in the record that disintegrins as a group are well-known to share a certain, specific, activity. Nothing in the specification indicates that Applicant was aware of any specific utility for the integral SVPH-1a metalloprotease of SEQ ID NO:12, or for its included disintegrin domain, which would permit its immediate use by the public at the time the

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application was filed. A method of using a material for further research to determine, e.g., its specific biological role, thus identifying or confirming a "real world" context for its use, cannot be considered to be a "substantial utility". *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966). The rejection of record is therefore sustained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-42 remain rejected for reasons of record under 35 U.S.C. § 112, first paragraph. Applicant's arguments filed 8 September 2006 have been fully considered but they are not persuasive. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The rejection of record is therefore sustained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
13 November 2006


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER